

### **REMARKS**

The Office Action mailed May 31, 2007 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 1-45 are pending in this application. Claims 4 and 26-45 are withdrawn from consideration. Each of the claim rejections previously responded to in the Response to Non-Final Office Action (hereinafter, "Response"), filed May 1, 2007, are repeated in the Office Action. Accordingly, Applicants incorporate by reference the arguments set forth in the Response and reply herein to the Response to Arguments set forth on p. 6 of the Office Action. Further, this reply is filed subsequent to the receipt of an Advisory Action, mailed August 22, 2007. Accordingly, Applicants include a reply to the comments included therein, following the reply to the Response to Arguments.

#### **Reply to the Response to Arguments**

The Office Action responds to three particular arguments made in the Response in item numbers 13, 14 and 15 (p. 6, Office Action). Taking each in order, Applicants provide the following rebuttal.

1. Bellotti does not anticipate claim 1 (Item 13)

Applicants asserted in the Response that USPN 4,596,571 to Bellotti et al. (hereinafter, "Bellotti") does not show or describe a catheter connector having a "tail extending from a proximal end of said body configured to receive a tube thereon," a feature recited in claim 1. In particular, Applicants pointed to the fact that reference numeral 22, indicated by the Office Action as the purported "tail," was identified by Bellotti as an "administration set," which is a well-known device in the medical device field. As such, Applicants pointed out that the figures in Bellotti with respect to the administration set are merely cut-away views, rather than the end of a purported "catheter connector" as alleged by the Office Action. The fact that cut-away views of the administration set were included is unsurprising as Bellotti is directed to a protective shroud for the connection between the administration set and solution container, as opposed to the administration set itself.

The Office Action states that the “examiner believes that the portion of the device signified by reference numeral 22 of Bellotti is capable of receiving a tube thereon.”

In reply, Applicants reiterate that Bellotti identifies reference numeral 22 as an administration set that is clearly shown as a cut-away view. Applicants submit that the allegation in the Office Action that the cut-away portion of the administration set 22 is “capable of receiving a tube thereon” is not a sufficient showing to establish a *prima facie* case of anticipation. Accordingly, claim 1 is not anticipated by Bellotti and is patentable over Bellotti. Elected dependent claims 2-3 and 5-20 are also patentable over Bellotti, because they are dependent on a patentable claim and also because they recite additional features not shown or described by Bellotti.

2. Combination of Fonger with Bellotti improper (Item 14)

Applicants included two reasons in the Response for the improper combination of USPN 5,190,528 to Fonger et al. (hereinafter, “Fonger”) with Bellotti: 1) tube 11 of Fonger is not a feature of a catheter connector body, and 2) it would not be obvious to a skilled artisan to substitute the rounded tube of Fonger for the spike 12 of Bellotti because the proposed modification would render Bellotti unsatisfactory for its intended purpose (i.e., the rounded spike 12 could not pierce through the membrane 24).

The Office Action addresses only the second of these points, stating that “the device of Bellotti does not say that a tapered point is required to puncture the septum...and it is conceivable that the septum need only a rigid member to puncture it” (p. 6, Office Action).

In reply, Applicants note that Bellotti shows and describes a “spike member 12” that during insertion “pierces the membrane 24” to open fluid communication between the administration set 22 and the contents of the container 20 (col. 2, ll. 65-68). Thus, the notion that it is “conceivable” that the septum need only a rigid member is inapposite as Bellotti clearly describes the septum as being “pierced” by a “spike member 12.” Consequently, Applicants submit that Bellotti describes a septum that cannot be penetrated by a rounded tube and, hence, the substitution of the Fonger rounded tube would render Bellotti unsatisfactory for its intended purpose. In any event, claim 8 is dependent on patentable claim 1 (in view of the above) and is therefore patentable.

3. *Prima facie* case of obviousness not established for claim 21 (Item 15)

In the Response, Applicants traversed the rejection of independent claim 21 as obvious over Bellotti in view of WO 02/058776 to Wilson et al. (hereinafter, “Wilson”) for two primary reasons: 1) a lack of suggested desirability to combine the Wilson cover with the Bellotti device, and 2) the absence in both Wilson and Bellotti of "a securement device attached at two separate locations" to a distal end of a catheter connector body.

The Office Action addressed only the first reason, stating that because Bellotti discloses “devices intended to surround and protect the connection site between fluid conduits” and because Bellotti describes use of the device “in a diverse number of environments” or “in the administration of parenteral fluids,” that the combination of Wilson and Bellotti is obvious.

In reply, Applicants first submit that the quoted passages of Bellotti in the Office Action do not contradict Applicants assertion of a lack of suggested desirability to combine Wilson with Bellotti. The shroud 18 is the feature of Bellotti that is intended to “surround and protect the connection site between fluid conduits.” As such, there is no suggested desirability to add another element (i.e., the cover of Wilson) to complicate the device for a redundant purpose. Further, the disclosure of “diverse environments” does not lead to the notion of a completely different device (i.e., a device “adapted for attachment to a patient” as recited in instant claim 21 rather than a device designed to “surround and protect the connection site” as described by Bellotti). Finally, the disclosure of “parenteral fluids” is not germane to the device but to the fluid within the solution container. As set forth in the Response, adding a covering adapted for attachment to a patient to the proximal end of an administration set intended to be suspended in air is not a desirable combination at least because the covering would serve no purpose.

Second, Applicants submit that neither Wilson nor Bellotti show or describe "a securement device attached at two separate locations" to a distal end of a catheter connector body, as recited in claim 21. As mentioned above, this salient point is not addressed in the Office Action. Applicants note that the repeated obviousness rejection in the Office Action does not indicate where in Wilson or Bellotti this feature is shown or described and, indeed, does not appear to mention this

feature at all. If this rejection is maintained, Applicants request in the interest of compact prosecution that the Office identify with specificity this feature in either Wilson or Bellotti to support a *prima facie* case of obviousness.

Thus, at least because there is a lack of desirability to combine Wilson with Bellotti and neither Wilson nor Bellotti show or describe “a securement device attached at two separate locations” to a distal end of a catheter connector body,” Applicants submit that a *prima facie* case of obviousness is not established. Accordingly, claim 21 is patentable over the combination of Bellotti and Wilson. Elected dependent claims 22-25 are also patentable over the combination of Bellotti and Wilson, because they are dependent on a patentable claim and also because they recite additional features not shown or described by the cited references.

### **Reply to Advisory Action Comments**

The Advisory Action states that the above arguments with respect to Bellotti are not convincing because, “[r]egardless of whether the figure [in Bellotti] is a cut away view or not, the tail extends from a proximal end of the body and, regardless of the length of this portion, is configured to receive a tube thereon.” An anticipation rejection must be supported by a showing of each and every element as set forth in the claim (MPEP 2131). The alleged “tail” is described in Bellotti as an administration set. There is no showing in Bellotti, expressly or inherently, that this administration set is “configured to receive a tube thereon” as claimed. Accordingly, Applicants respectfully submit that a *prima facie* case of anticipation has not been established.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and

authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 480062004300. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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